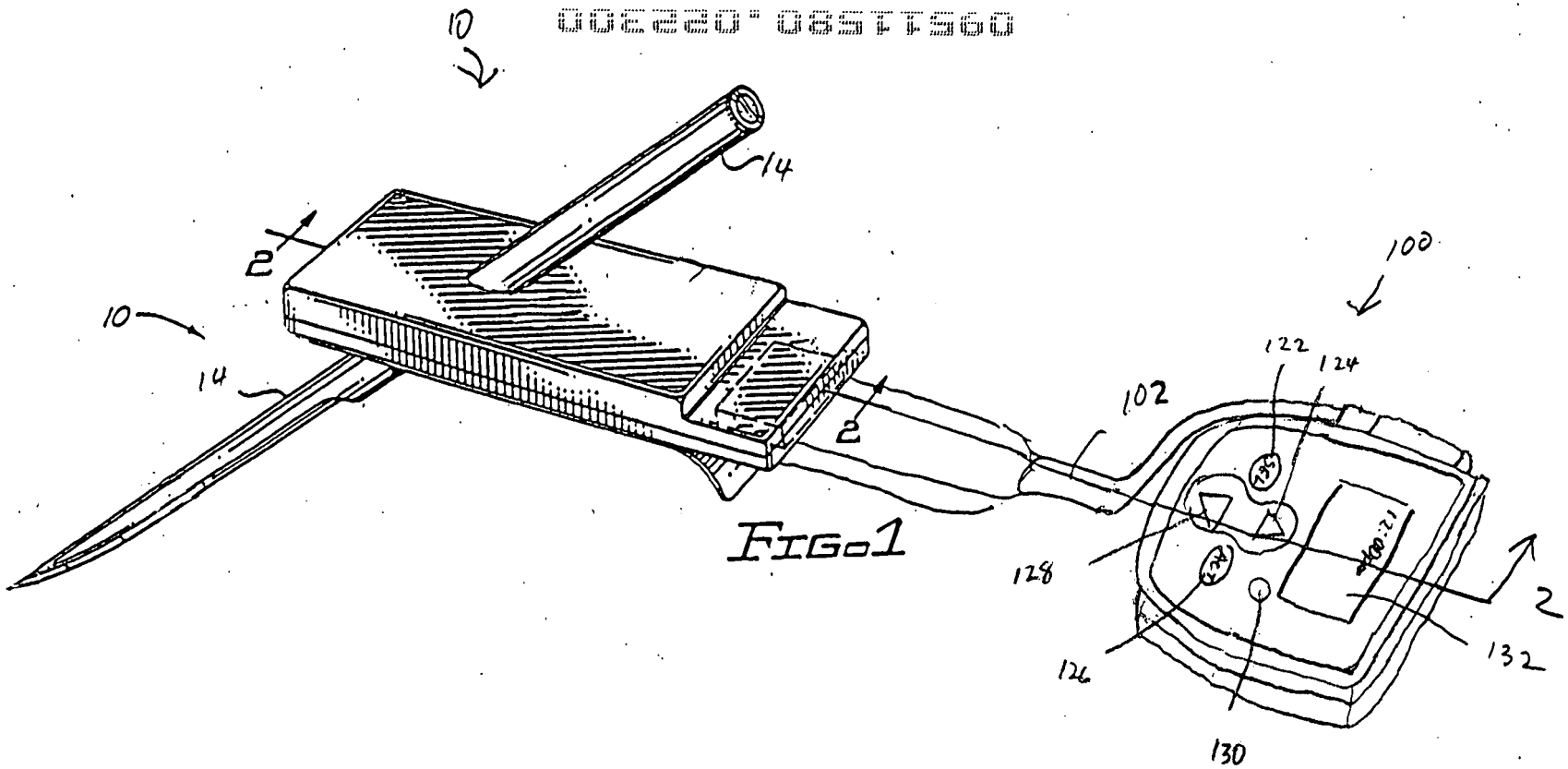


FIG. 1

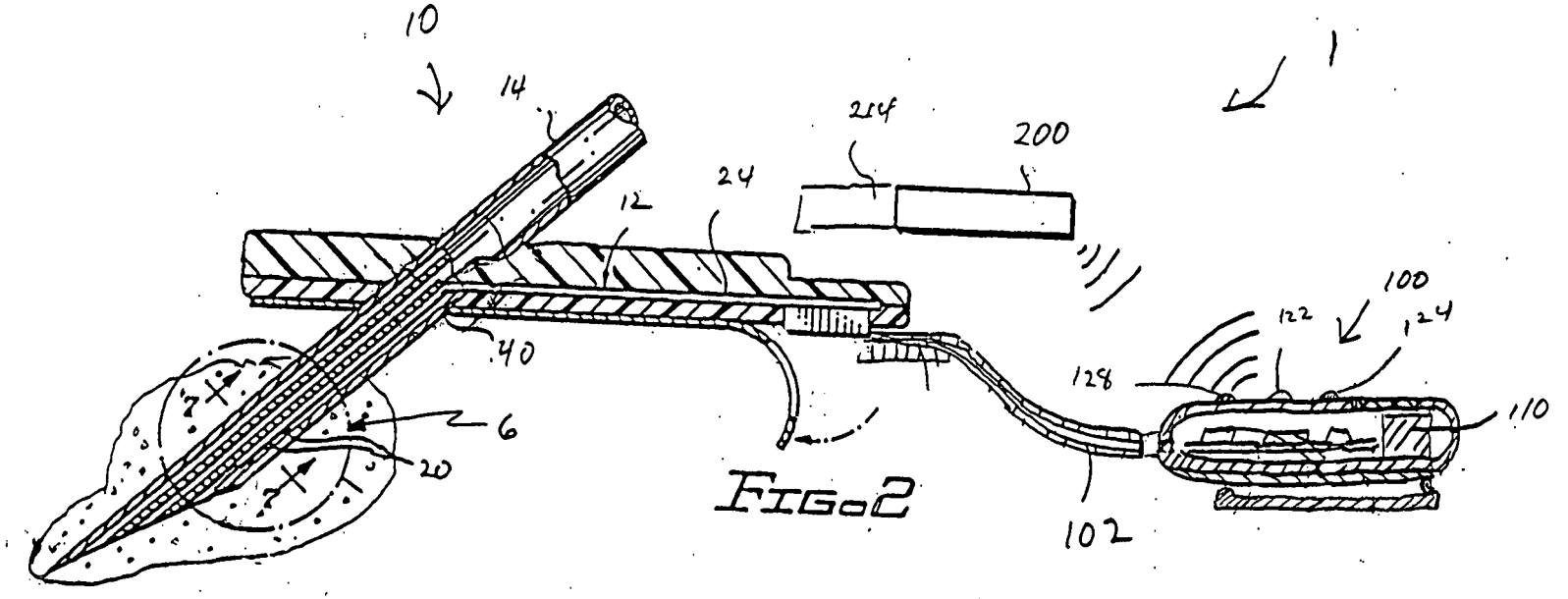


FIG. 2

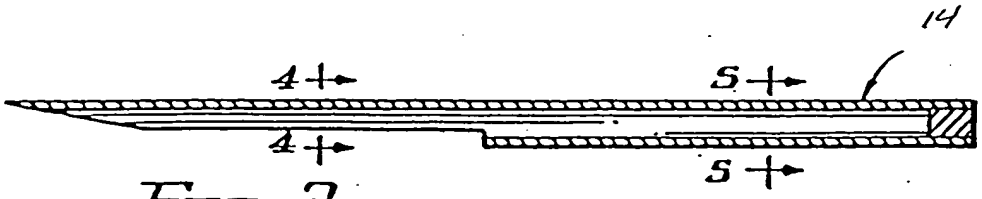


FIG. 3

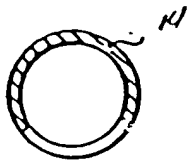


FIG. 4

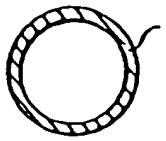


FIG. 5

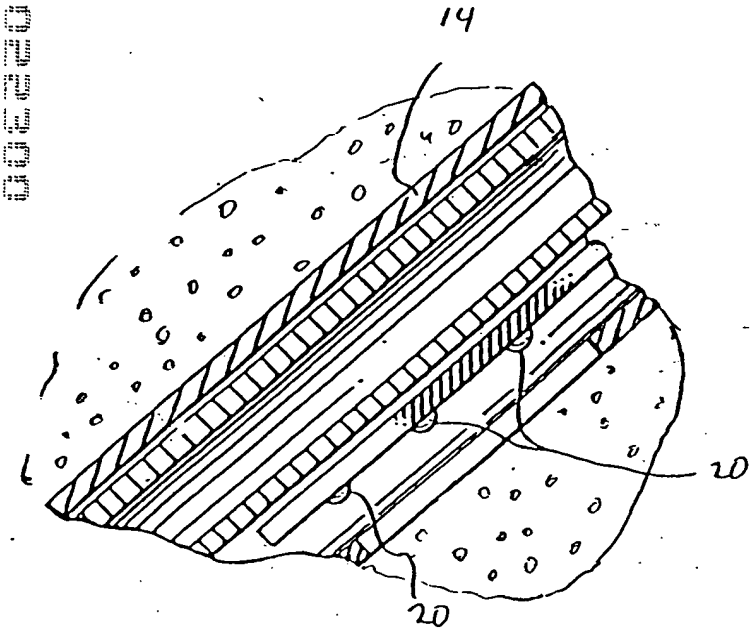


FIG. 6

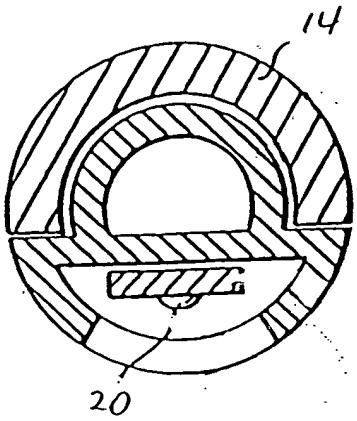


FIG. 7

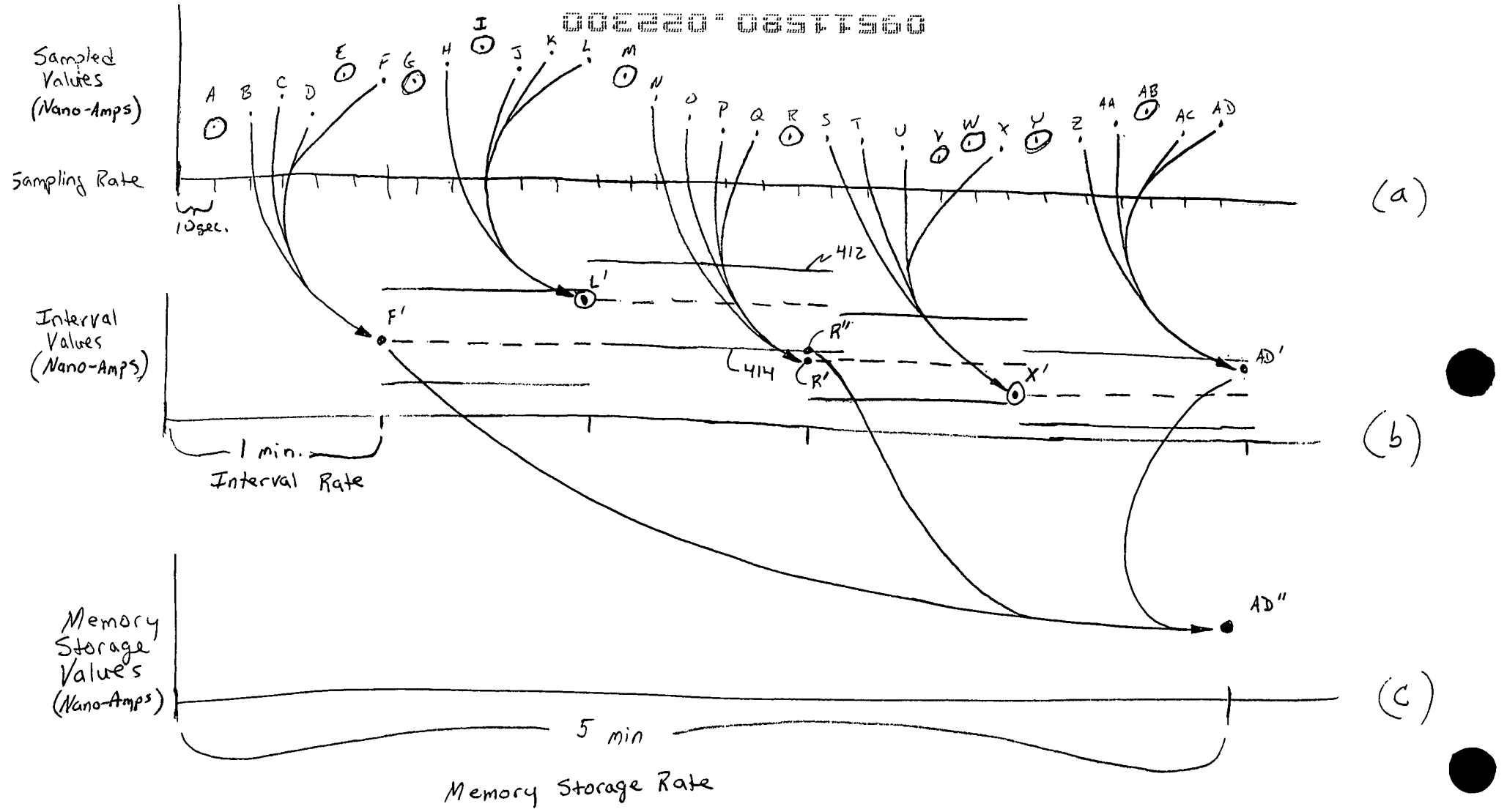

Sampled Values (Nano-Amps)
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z AA AB AC AD
Sampling Rate
10sec.
(a)
412
L'
F'
R''
R'
414
X'
AD'
AD''
1 min.
Interval Rate
Interval Values (Nano-Amps)
(b)
Memory Storage Values (Nano-Amps)
(c)
5 min
Memory Storage Rate

Fig. 8

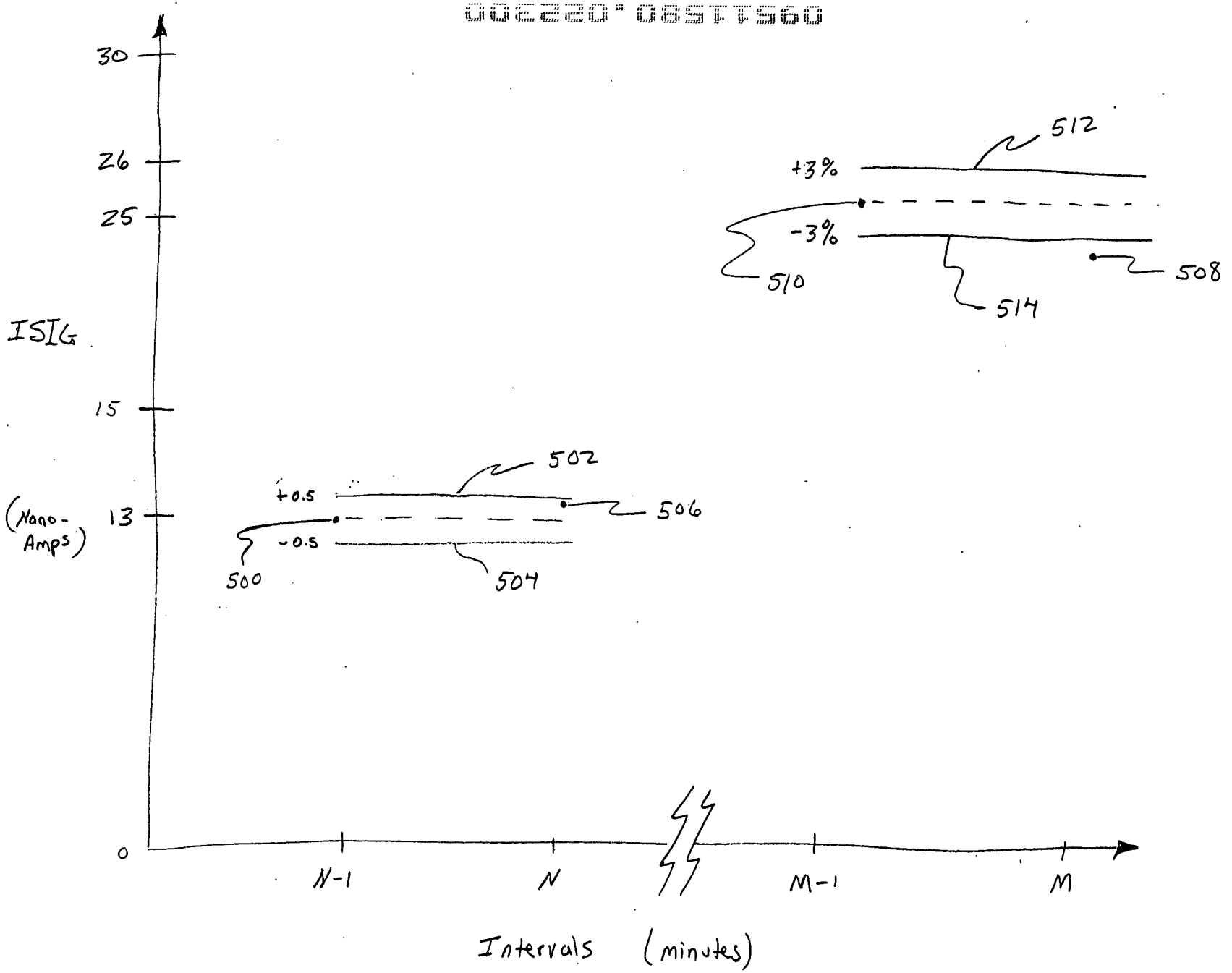
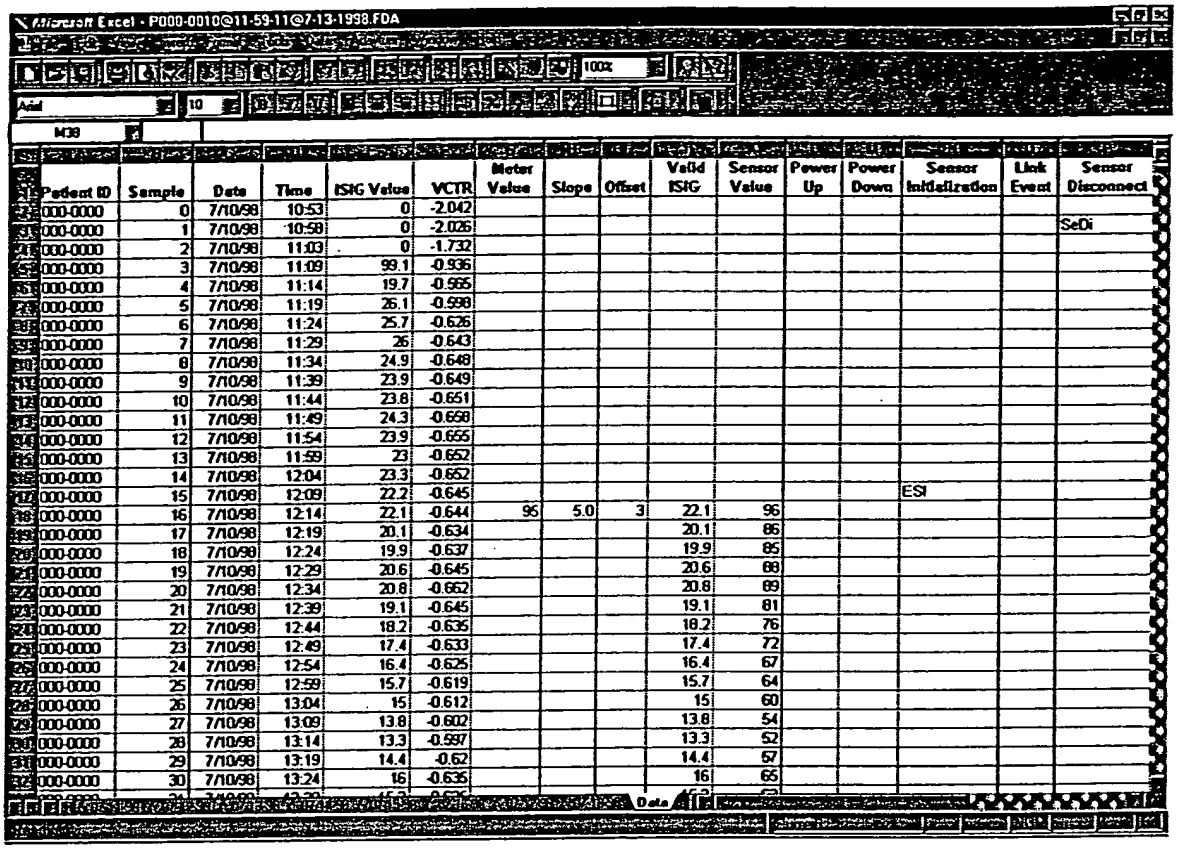


Fig. 9



Microsoft Excel - P000-0010@11-59-11@7-13-1998.FDA

Patient ID	Sample	Date	Time	ISIG Value	VCTR	Meter Value	Slope	Offset	Valid ISIG	Sensor Value	Power Up	Power Down	Sensor Initialization	Link Event	Sensor Disconnect
000-0000	0	7/10/98	10:53	0	-2.042										
000-0000	1	7/10/98	10:58	0	-2.026										SeDi
000-0000	2	7/10/98	11:03	0	-1.732										
000-0000	3	7/10/98	11:09	99.1	-0.936										
000-0000	4	7/10/98	11:14	19.7	-0.965										
000-0000	5	7/10/98	11:19	26.1	-0.998										
000-0000	6	7/10/98	11:24	25.7	-0.626										
000-0000	7	7/10/98	11:29	26	-0.643										
000-0000	8	7/10/98	11:34	24.9	-0.648										
000-0000	9	7/10/98	11:39	23.9	-0.649										
000-0000	10	7/10/98	11:44	23.8	-0.651										
000-0000	11	7/10/98	11:49	24.3	-0.658										
000-0000	12	7/10/98	11:54	23.9	-0.655										
000-0000	13	7/10/98	11:59	23	-0.652										
000-0000	14	7/10/98	12:04	23.3	-0.652										
000-0000	15	7/10/98	12:09	22.2	-0.645								ESI		
000-0000	16	7/10/98	12:14	22.1	-0.644	95	5.0	3	22.1	96					
000-0000	17	7/10/98	12:19	20.1	-0.634				20.1	86					
000-0000	18	7/10/98	12:24	19.9	-0.637				19.9	85					
000-0000	19	7/10/98	12:29	20.6	-0.645				20.6	88					
000-0000	20	7/10/98	12:34	20.8	-0.662				20.8	89					
000-0000	21	7/10/98	12:39	19.1	-0.645				19.1	81					
000-0000	22	7/10/98	12:44	18.2	-0.636				18.2	76					
000-0000	23	7/10/98	12:49	17.4	-0.633				17.4	72					
000-0000	24	7/10/98	12:54	16.4	-0.625				16.4	67					
000-0000	25	7/10/98	12:59	15.7	-0.619				15.7	64					
000-0000	26	7/10/98	13:04	15	-0.612				15	60					
000-0000	27	7/10/98	13:09	13.8	-0.602				13.8	54					
000-0000	28	7/10/98	13:14	13.3	-0.597				13.3	52					
000-0000	29	7/10/98	13:19	14.4	-0.62				14.4	57					
000-0000	30	7/10/98	13:24	16	-0.635				16	65					

Fig. 10

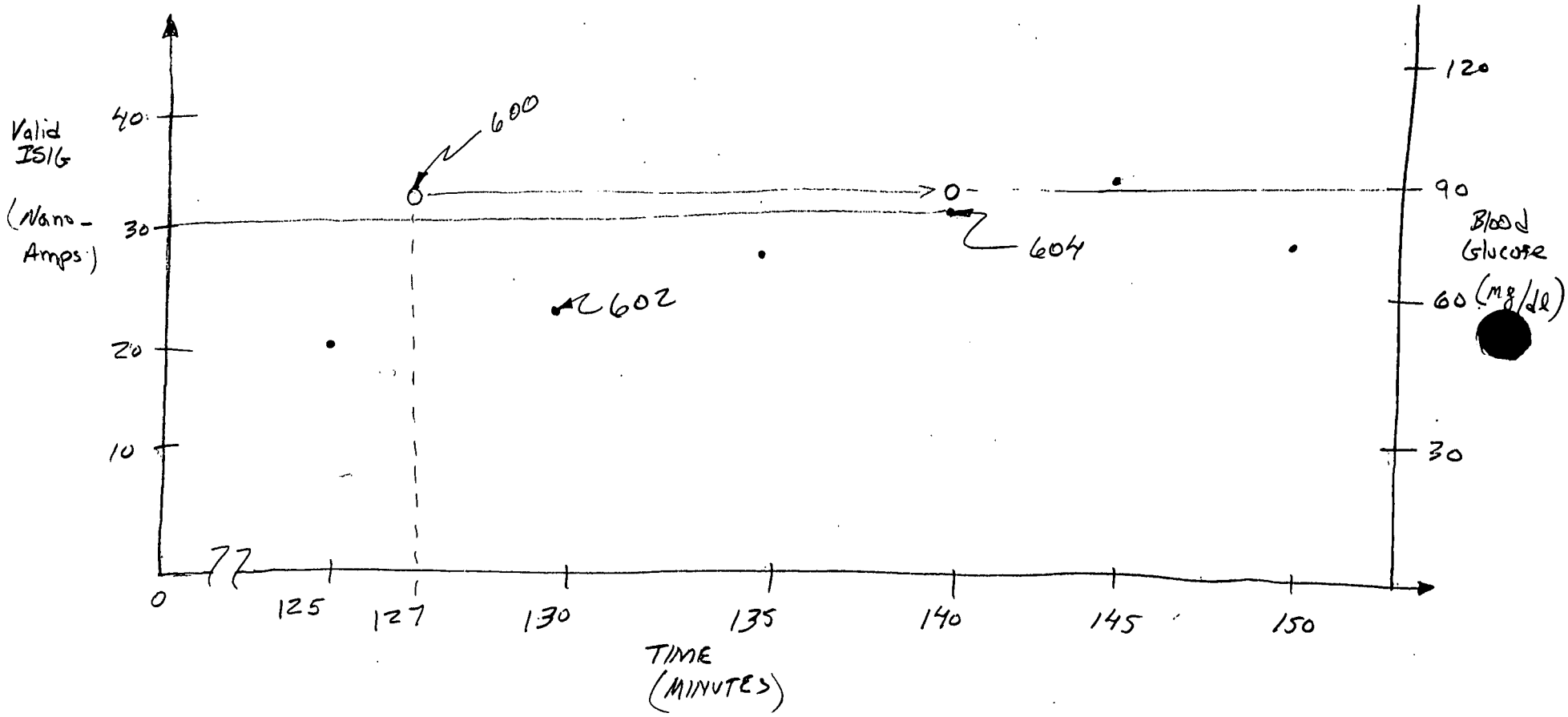


Fig. 11

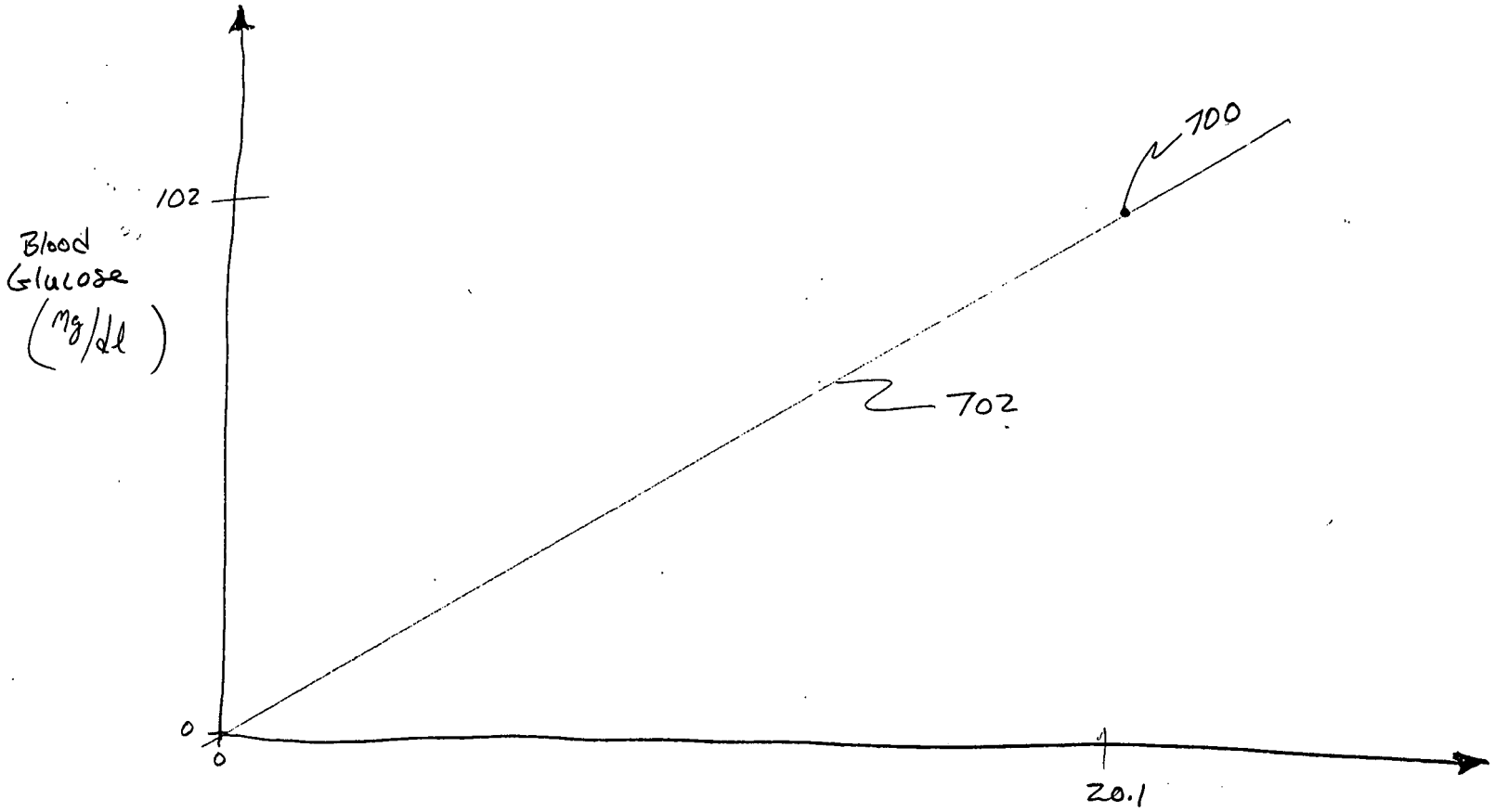


Fig. 12

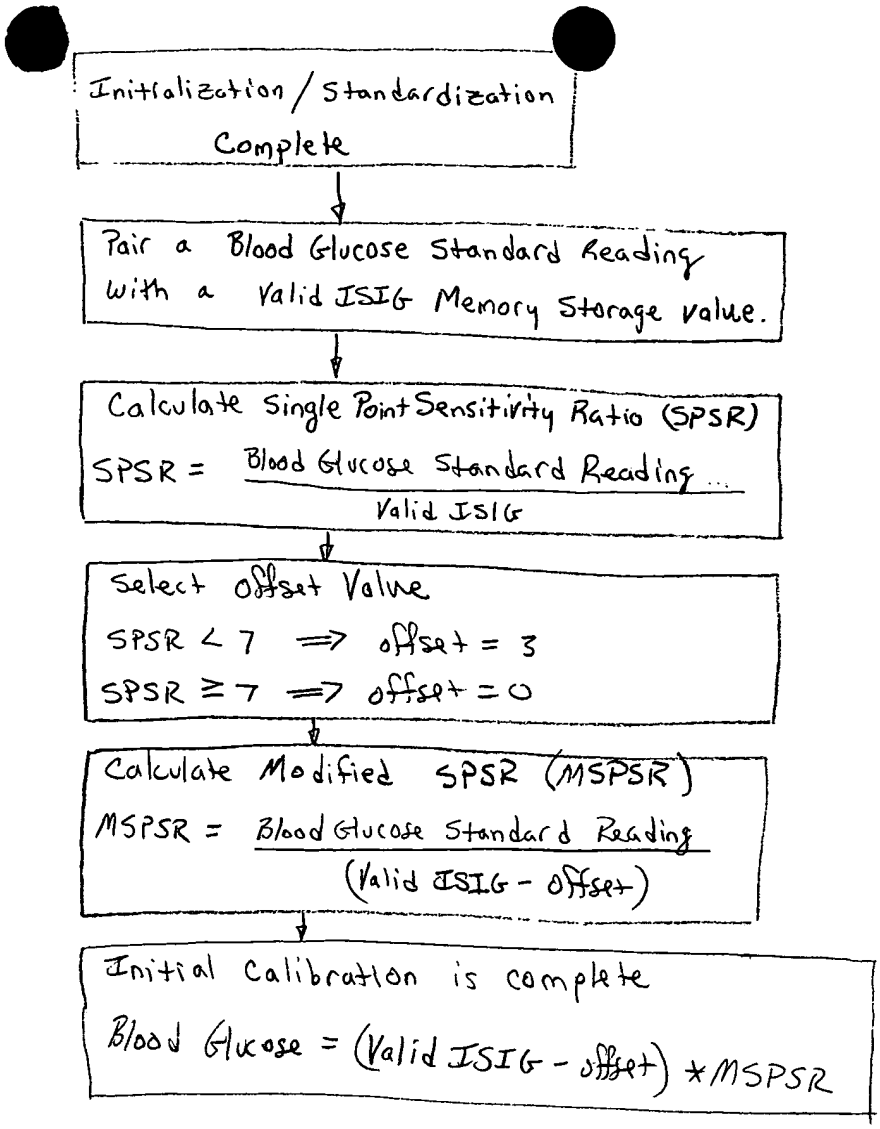

Initialization / Standardization Complete
Pair a Blood Glucose Standard Reading with a Valid ISIG Memory Storage value.
Calculate Single Point Sensitivity Ratio (SPSR)
SPSR = Blood Glucose Standard Reading / Valid ISIG
Select offset Value
SPSR < 7 ⇒ offset = 3
SPSR ≥ 7 ⇒ offset = 0
Calculate Modified SPSR (MSPSR)
MSPSR = Blood Glucose Standard Reading / (Valid ISIG - offset)
Initial Calibration is complete
Blood Glucose = (Valid ISIG - offset) * MSPSR

Fig. 13

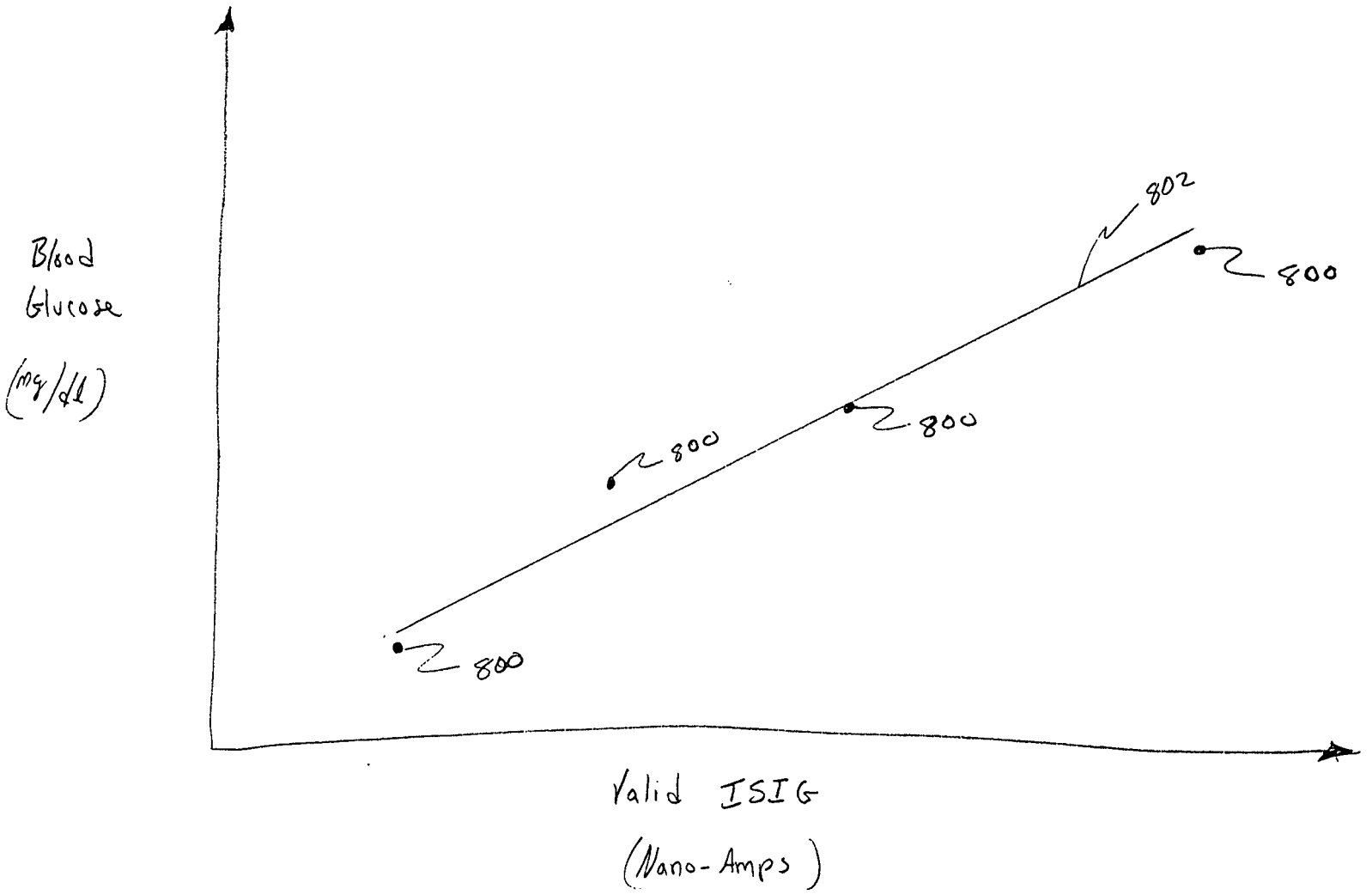


Fig. 14

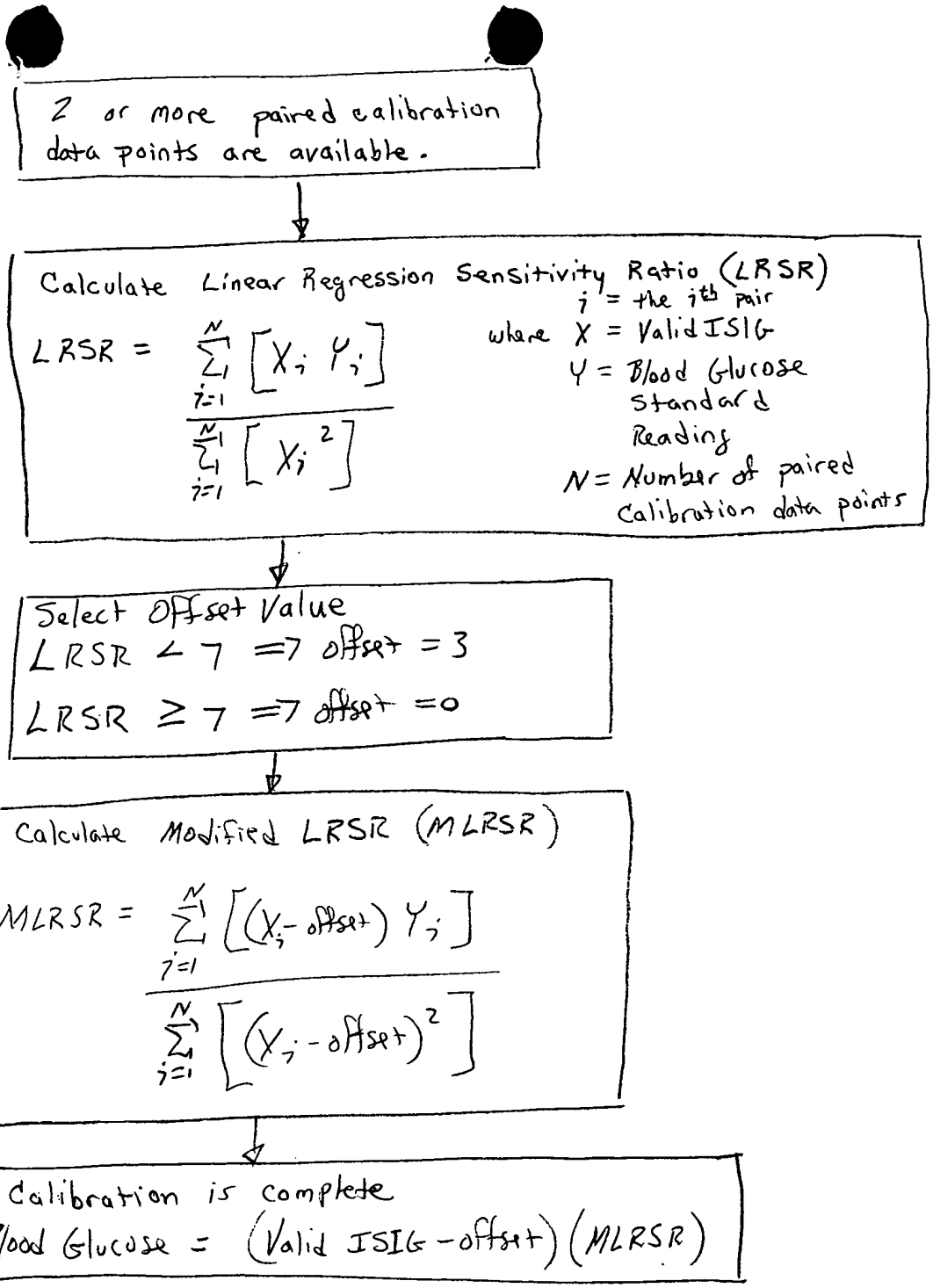

2 or more paired calibration data points are available.
Calculate Linear Regression Sensitivity Ratio (LRSR)
$LRSR = \frac{\sum_{i=1}^{N} [X_i Y_i]}{\sum_{i=1}^{N} [X_i^2]}$
where i = the ith pair
X = Valid ISIG
Y = Blood Glucose Standard Reading
N = Number of paired Calibration data points
Select Offset Value
LRSR < 7 ⇒ offset = 3
LRSR ≥ 7 ⇒ offset = 0
Calculate Modified LRSR (MLRSR)
$MLRSR = \frac{\sum_{i=1}^{N} [(X_i - offset) Y_i]}{\sum_{i=1}^{N} [(X_i - offset)^2]}$
Calibration is complete
Blood Glucose = (Valid ISIG - offset)(MLRSR)

Fig. 15